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DEPARTMENT OF EDUCATION

34 CFR Chapter III

Proposed priority--National Institute on Disability and Rehabilitation Research-- Traumatic Brain Injury Model Systems Centers Collaborative Research Project

[CFDA Number: 84.133A-7.]

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Proposed priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR).

Specifically, this notice proposes a priority for a Disability and Rehabilitation Research Project (DRRP) on Traumatic Brain Injury Model Systems Centers Collaborative Research Projects. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2013 and later years. We take this action to focus research attention on areas of national need. We intend this priority to contribute to improved employment outcomes for individuals with disabilities.

DATES: We must receive your comments on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Address all comments about this notice to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue, SW., room 5133, Potomac Center Plaza (PCP), Washington, DC 20202-2700.

If you prefer to send your comments by email, use the following address: marlene.spencer@ed.gov. You must include the phrase "Proposed Priority for Traumatic Brain Injury Model Systems Centers Collaborative Research Projects" in the subject line of your electronic message. FOR FURTHER INFORMATION CONTACT: Marlene Spencer. Telephone: (202) 245-7532 or by email: marlene.spencer@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

This notice of proposed priority is in concert with NIDRR's Long-Range Plan (Plan). The Plan, which was published in the Federal Register on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site:

<http://www2.ed.gov/legislation/FedRegister/other/2006-1/021506d.pdf>.

Through the implementation of the currently approved Plan, NIDRR seeks to: (1) improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training methods to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms for integrating research and practice; and (6) disseminate findings.

This notice proposes a priority that NIDRR intends to use for a DRRP competition in FY 2013 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award using this priority. The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority,

we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in room 5133, 550 12th Street, SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under FOR FURTHER INFORMATION CONTACT.

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation technology, that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to improve the effectiveness of services authorized under the Rehabilitation Act by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR

350.13 through 350.19: research, training, demonstration, development, utilization, dissemination, and technical assistance.

An applicant for assistance under this program must demonstrate in its application how it will address, in whole or in part, the needs of individuals with disabilities from minority backgrounds (34 CFR 350.40(a)). The approaches an applicant may take to meet this requirement are found in 34 CFR 350.40(b). Additional information on the DRRP program can be found at: www.ed.gov/rschstat/research/pubs/res-program.html#DRRP.

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

PROPOSED PRIORITY:

This notice contains 1 proposed priority.

Traumatic Brain Injury Model Systems Centers
Collaborative Research Projects.

Background:

The Centers for Disease Control and Prevention reports that approximately 1.7 million traumatic brain injuries (TBIs) were recorded annually between 2002 and 2006 (Faul et al., 2010). Of the persons incurring these TBIs, approximately 50,000 died, 275,000 were hospitalized, and 1.37 million were treated and released from emergency

departments. These estimates do not include those individuals who sustained a TBI and failed to seek medical care, those treated in primary care settings, and those treated in military and Veterans Affairs hospitals. The Department of Defense reports that 235,046 service members were diagnosed with TBIs between 2000 and the end of 2011 (Defense and Veterans Brain Injury Center, 2012). The three leading causes of TBI for civilians are falls, motor vehicle accidents, and struck by/against events (i.e., events in which an individual collides with a moving or stationary object). The leading cause of TBI for military personnel is explosions/blasts (Sayer et al., 2008).

Persons who sustain moderate to severe TBIs often require intensive medical treatment. Forty percent of those hospitalized with nonfatal TBIs experience impairments that result in long-term disability (Corrigan, Selassie, & Orman, 2010). Common disabilities resulting from TBIs include problems with cognition, sensory processing, communication, and behavioral or mental health (National Institute of Neurological Disorders and Stroke (NINDS), 2002). Some TBI survivors develop physical complications, some of which may not become apparent until long after the injury (NINDS, 2002).

There have been several initiatives in recent years to review and synthesize the available evidence on outcomes following TBI (e.g., Guillaumondegui et al., 2011; Institute of Medicine (IOM), 2008) and on the effectiveness of rehabilitation treatments for TBI (e.g., Brasure et al., 2012; IOM, 2011). There are, however, significant challenges to conducting and synthesizing research on these topics such as the complexity of the condition, the significant number of factors that affect recovery in this population, and the complexity of the interventions (Brasure et al., 2012). Experts agree that there remains a strong need for future research to better establish the evidence base for rehabilitation interventions for this population (Brasure et al., 2012).

The Traumatic Brain Injury Model Systems (TBIMS) program was created by NIDRR in 1987 to demonstrate the benefits of a coordinated system of neurotrauma and rehabilitation care and to conduct innovative research on all aspects of care for those who sustain TBIs. For purposes of the TBIMS, TBI is defined as damage to brain tissue caused by an external mechanical force as evidenced by loss of consciousness or post-traumatic amnesia due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical or mental

status examination. Both penetrating and non-penetrating wounds that fit these criteria are included, but primary anoxic encephalopathy is not.

NIDRR currently funds 16 TBIMS centers throughout the United States. These centers provide comprehensive systems of brain injury care to individuals who sustain TBIs and conduct TBI research, including clinical research and the analysis of standardized data in collaboration with other related projects. The mission of the TBIMS is to improve the lives of persons who experience TBIs, and to help their families and communities, by creating and disseminating new knowledge about the natural course of TBI and rehabilitation treatment and outcomes following TBI.

Since 1989, the TBIMS centers have collected and contributed information on common data elements for a centralized TBIMS database, which is maintained through a NIDRR-funded grant for a National Data and Statistical Center for the TBIMS. (Additional information on the TBIMS database can be found at <https://www.tbindsc.org>.) The TBI National Data and Statistical Center for the TBIMS coordinates data collection, manages the TBIMS database, and provides statistical support to the model systems projects. As of September 2012, the TBIMS centers have

contributed 11,247 cases to the TBIMS database, with follow-up data extending 20 years after injury.

In 2003 and again in 2008, NIDRR leveraged the capacity of the TBIMS program by funding large-scale collaborative research projects that required participation across TBIMS centers. The collaborative projects funded in 2008 included a randomized controlled trial of the effectiveness of amantadine hydrochloride in treating post-TBI irritability and aggression and a practice-based study of factors that predict the effectiveness of rehabilitation interventions following TBI. Through the funding of this priority, the TBIMS program will continue to serve as a platform for multi-site research that contributes to evidence-based rehabilitation interventions and improves the lives of individuals with TBIs.

References

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war on terror. Archives of Physical Medicine and Rehabilitation, 89(1), 163-70.

Proposed Priority:

The Assistant Secretary for Special Education and Rehabilitative Services establishes a priority for the funding of Disability and Rehabilitation Research Projects (DRRPs) to serve as Traumatic Brain Injury Model Systems (TBIMS) multi-site collaborative research projects. To be eligible under this priority, an applicant must have received a grant under the TBIMS centers priority (see <https://www.federalregister.gov/articles/2012/06/11/2012-14115/disability-and-rehabilitation-research-projects-and-centers-program-traumatic-brain-injury-model>). Each TBIMS multi-site collaborative research project must be designed to contribute to evidence-based rehabilitation interventions and clinical practice guidelines that improve the lives of individuals with traumatic brain injuries (TBIs) through research, including the testing of approaches to treating TBIs or the assessment of the outcomes of individuals with TBIs. Each TBIMS multi-site collaborative research project must contribute to this outcome by--

(a) Collaborating with three or more of the NIDRR-funded TBIMS centers (for a minimum of four TBIMS sites).

In addition to the required TBIMS sites, applicants may also propose to include other TBI research sites that are not currently participating in the TBIMS program;

(b) Conducting multi-site research on questions of significance to TBI rehabilitation, using clearly identified research designs. The research must focus on outcomes in one or more of the following domains identified in NIDRR's Long-Range Plan, published in the Federal Register on February 15, 2006 (71 FR 8165): health and function, participation and community living, technology, and employment;

(c) Demonstrating the capacity to carry out multi-site collaborative research projects, including administrative capabilities, experience with management of multi-site research protocols, and demonstrated ability to maintain standards for quality and confidentiality of data gathered from multiple sites;

(d) Addressing the needs of people with disabilities, including individuals from traditionally underserved populations;

(e) Coordinating with the NIDRR-funded Model Systems Knowledge Translation Center to provide scientific results and information for dissemination to clinical and consumer audiences; and

(f) Ensuring participation of individuals with disabilities in conducting TBIMS research.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the Federal Register. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority:

We will announce the final priority in a notice in the Federal Register. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the Federal Register.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may--

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal

governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency--

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account--among other things and to the extent practicable--the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives--such as user fees or marketable permits--to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that

might result from technological innovation or anticipated behavioral changes."

We are issuing this proposed priority only upon a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Program have been well established over the years. Projects similar to the new DRRP have been completed successfully, and the new DRRP, established consistently with the proposed priority, is

expected to improve the lives of individuals with disabilities and generate through research and development, disseminate, and promote the use of new information that would improve the lives of individuals with disabilities who have experienced TBIs.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 5075, PCP, Washington, DC 20202-2550. Telephone: (202) 245-7363. If you use a TDD or a TTY, call the FRS, toll free, at 1-800-877-8339.

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Dated: February 25, 2013

Michael Yudin,
Acting Assistant Secretary for
Special Education and
Rehabilitative Services.

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